

Theresa Lonhoff-Garrett  
109 Webster Ave.  
Morgantown WV 26501-6858  
304-292-1279

7222 '99 MAY 25 AIO 54  
May 19, 1999

Dockets Management Branch (HFA-305)  
Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857-0003

RE: Docket No. 98N-1265

Dear Sir/Madam:

This is my first letter to your agency. I am a mother, a student in special education, & stake & compounded prescriber. It is my understanding that the FDA is contemplating restrictions upon the use of compounded medicines by consumers, (in the Memorandum of Understanding of 1/21/99, & Compounding Section 503A of the Modernization Act.)

Due to my being diagnosed with osteoporosis, I require a compounded estrogen/progesterone prescription. The ratio of these is balanced in a certain way to promote the growth of new osteoblasts (bone cells). The estrogen is a mixture of three types of estrogens, from natural sources, in the same ratio as the female body produces them in the pre-menopausal years. It is important to me that they be done this way to minimize the risk of adverse side effects, such as breast cancer. It is important to me that they be from natural sources because I have serious ethical problems with the production methods & content of Premarin.

Please do not do anything which would limit my ability

98N-1265

2648

to choose the type of prescription that my physician & I feel is best for me.

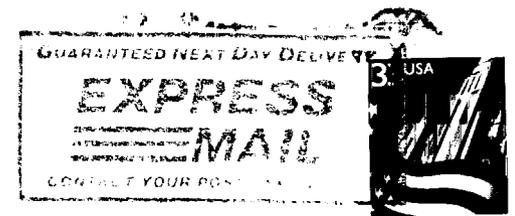
Please amend the Memorandum of Understanding of 1/31/99, as well as the Section 503A. I would like to see your agency working on things that are actually safety issues - like the danger of aspartame & other questionable synthetic food additives.

Please respond to this letter as soon as possible.

Sincerely,

Theresa Imhoff-Barnett

109 Webster Ave.  
Morgentron WV 26501



Sockets + Management Branch (HFA-305)  
Food + Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857-0003

20857+0003

